

Submitter:
USHIFU, LLC

USHIFU Stepper
Traditional 510(k)

510(k) SUMMARY**JUN 11 2008**

Submitter Name:	USHIFU, LLC
Submitter Address:	1450 South Woodland Blvd. DeLand, FL 32720
Contact Person:	Mare Ryan Vice President of Regulatory Affairs
Phone Number:	386.785.0100
Fax Number:	386.785.0101
Date Prepared:	April 4, 2008
Device Trade Name:	USHIFU Stepper
Device Common Name:	Ultrasound Probe Stepper
Classification Number:	21 CFR 892.1570
Classification Name:	Transducer, Ultrasonic, Diagnostic
Product Code:	ITX
Predicate Device:	K843573, Super Scan/Biopsy Guide, CIVCO
Statement of Intended Use:	The USHIFU Stepper is intended to provide support and stabilization for an ultrasonic probe during prostate imaging.
Device Description:	The USHIFU Stepper is a mechanical device which is manually controlled in the horizontal and vertical directions. It is designed to allow for finite adjustments in these planes. It is composed of light-weight materials, is pre-assembled and easily attached to a surgical table.
Comparison to the Predicate Device:	Based upon the intended use, design, and composition (materials), it can be concluded the USHIFU Stepper is substantially equivalent to the predicate device in terms of intended use, safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 11 2008

Ms. Mare Ryan
Vice President, Regulatory Affairs
USHIFU Development Company, LLC
1450 South Woodland Blvd.
DELAND FL 32720

Re: K080970
Trade/Device Name: USHIFU Stepper
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: April 4, 2008
Received: April 4, 2008

Dear Ms. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

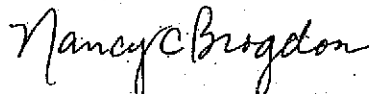
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

K080970

Device Name:

USHIFU Stepper

Indications for Use:

The USHIFU Stepper is intended to provide support and stabilization for an ultrasonic probe during prostate imaging.

Prescription Use x
(Part 21 CFR 801 Subpart D)

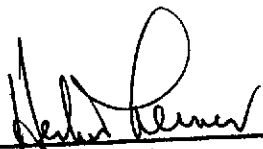
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080970